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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,764	11/15/2000	Heinz-Josef Lenz	13761-0739	7045
23639	7590	12/01/2005	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			SITTON, JEHANNE SOUAYA	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 09/715,764	Applicant(s) LENZ ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none.
- Claim(s) objected to: none.
- Claim(s) rejected: 47-67.
- Claim(s) withdrawn from consideration: none.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Attachment

1. The proposed amendment filed 11/10/2005 will not be entered because it raises new issues that would require further search and consideration and new grounds of rejection. The amendments to include: “correlating genotype” in claim 47 (the 3/05 claims were directed to correlating expression), “determining the genotype in the subject’s biological sample” in claim 47 (the 3/05 claim limited to particular types of cells), “a TS gene” in claim 47, “biological sample consist of tumor cells or normal cells” in claim 48 (broader than 3/05 claims), “if present at a tandemly repeated 28 base pair sequence” in claim 57 (not found in the 3/05 claim) specifically raise new issues and require further search and consideration. Further, proposed claim 66 recites “the extratumoral cells” which lack antecedent basis and would require new grounds of rejection. Additionally, the previous claims were drawn to determining the genotype in extratumoral, non metastatic cells, however the scope of the claims has been broadened to include genotyping any biological sample, including tumor cells or normal cells. Such broadening requires further search and consideration and does not simplify the issues as it raises new issues.
2. All previous rejections made in the office action mailed 6/6/05 are maintained.
3. It is noted that the response has not addressed the rejection made under 35 USC 112/first paragraph over claim 67.
4. At page 6, the response traverses that the claim 57 is directed to a kit for use in screening effectiveness of TS directed drug therapy. This argument has been thoroughly reviewed but was not found persuasive, as the use for a kit carries no patentable weight. The response’s arguments at pages 6-8 directed to the non-entered claims will not be considered as they are not drawn to

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the instantly pending claims. At page 9, the response traverses the rejection of claims 47-56 and 61-67 made under 35 USC 103 at section 12 of the previous office action. The response asserts that Horie only identifies a TS polymorphism, and teaches away by stating that the polymorphism in the 5' terminal region is found in normal individuals and that the polymorphism might not be related to any abnormal physical condition. This argument as been thoroughly reviewed but was not found persuasive. The rejection was not made over the teachings of Horie alone. While Horie teaches that "there are no data to suggest that the polymorphism *might* be related to any abnormal physical condition", Horie does not teach that it is not associated with abnormal physical condition. Horie teaches that the polymorphism is associated with altered expression activity of the gene and Leichman teaches that expression levels of TS correlated with sensitivity to 5'FU in subjects. Therefore, the rejection did not only set forth an invitation to experiment, as is asserted in the response. This argument is therefore not found persuasive. The arguments made at pages 10-11, regarding the rejection of claim 57-60 made at section 13 of the previous office action, have been fully considered as they relate to the instantly pending claims. The response's assertion that claims are directed to a kit for use in screening for the effectiveness of TS directed drug therapy are not found persuasive because the use for a kit carries no patentable weight. Any arguments made at pages 9-11 of the response regarding the non-entered claims have not been considered, as they are not directed to the instantly pending claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

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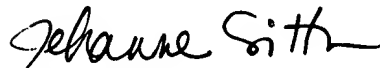
0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

11/22/05